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M/J

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/327, 230 06/07/99 GRAY

J 5718-4A

000826
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HM22/0811

EXAMINER

NELSON, A

ART UNIT	PAPER NUMBER
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1638

DATE MAILED:

08/11/00

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/327,230	Applicant(s) John Gray, et al.
	Examiner Amy Nelson	Group Art Unit 1638

Responsive to communication(s) filed on Jun 7, 1999.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1-23 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 1-23 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1638.
2. The Drawing filed 6/7/99 has been approved by the Draftsperson.

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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5. Claims 1-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is drawn broadly toward an isolated promoter from a plant cell death suppressor gene, as well as vectors, transformed host cells and transgenic plants comprising said promoter. Applicant describes a single lethal leaf spot gene (*lls1*) from maize, and describes the 5' upstream region for said gene (SEQ ID NO:1). Applicant does not show that the upstream region has promoter activity, and hence Applicant does not describe a promoter *per se*. Also, Applicant does not describe the composition or structure of other promoter sequences from other plant cell death suppressor genes, and hence it is not clear from the instant specification that the Applicant was in possession of the invention.

See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

6. Claims 1-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant broadly claims an isolated promoter from a plant cell death suppressor gene, as well as vectors, transformed host cells and transgenic plants comprising said promoter.

Applicant teaches mapping and transposon tagging of the maize mutant, *lls1* (lethal leaf spot), which causes necrotic lesions, and characterization of the gene. In particular, Applicant teaches characterization of the 5' upstream region (SEQ ID NO:1). Applicant teaches that the gene has sequence similarity with an EST from *Arabidopsis thaliana*, and maps to the same location as *dd1* (drop dead) from sorghum. Applicant also teaches that *lls1* lesions occur randomly on developmentally competent areas of the leaf, and are triggered by cell death induced by an incompatible pathogen or physical wounding (Example 1). Applicant teaches that the encoded LSS1 protein contains two motifs conserved in bacterial phenolic dioxygenases, especially aromatic ring-hydroxylating (ARH) dioxygenases. Applicant teaches that whereas sporulating lesions are formed in *lls1* mutant plants upon infection with *Puccinia sorghi*, non-sporulating lesions are formed upon infection with either *Cochliobolus carbonum* or *C. heterotrophus* (Exasmple 1). Finally, Applicant teaches by Northern analysis the pattern of tissue specific expression of the *lls1* gene, and teaches that the gene is induced by wounding and by infection with *Helminthosporium carbonum* (Example 2).

Applicant does not teach that the isolated 5' upstream region of SEQ ID NO:1 has promoter activity, and can activate expression of an operably linked coding sequence. Hence,

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Applicant has not disclosed an isolated promoter *per se*. Moreover, Applicant has not taught other promoters from other plant cell death suppressor genes as broadly claimed.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

The state of the art for isolation of promoter sequences with a defined activity is highly unpredictable. Significant guidance is required with regard to hybridization/wash conditions and/or PCR conditions that will allow isolation of functionally related promoter sequences with similar activity. The region of a given promoter which has a specific activity can not be predicted, and involves the complex interaction of different subdomains (Benfey *et al.*; Science 250: 959-966, 1990, see Abstract, Fig. 3-5). Even a very small region may be critical for activity, and the criticality of a particular region must be determined empirically (Kim *et al.*; Plant Mol. Biol. 24: 105-117, 1994, Abstract, Tables 1-4, Fig. 1-2). Often different promoters from a family of genes have different transcriptional activity.

Applicant has isolated a 5' upstream region from a single maize *l1s1* gene. Applicant has not demonstrated that the isolated region (*i.e.* SEQ ID NO:1) has promoter activity, and Applicant has not specifically defined the activity of the putative promoter in terms of level of

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activity, tissue specificity, or necessary or sufficient regions of the promoter for activity. The putative promoter fragment has not been shown by Applicant to possess transcriptional activity, and hence is not enabled as a promoter *per se*. Also, given the failure of Applicant to provide guidance for isolation of other functionally related cell death suppressor gene promoters, undue trial and error experimentation would be required to screen through the vast number of promoter fragments from any plant species to identify those that are related to the putative promoter fragment of SEQ ID NO:1.

When the *Wands* factors are weighed it is concluded that undue experimentation would be required to practice the invention, and therefore the invention is not enabled.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At Claim 1, line 2, the phrase “is capable of driving” is indefinite because it is unclear whether or not the promoter drives expression of a gene. The phrase should be changed to --drives--.

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Claim 2 is indefinite, because the claim is dependent on itself. A claim cannot depend from itself. If Applicant intends "The promoter of claim 1," then the phrase lacks proper antecedent basis, because claim 1 is directed to an isolated nucleotide sequence.

At Claim 3, line 1, "the promoter of claim 1" lacks proper antecedent basis, because claim 1 is directed to an isolated nucleotide sequence.

Claim 4 is unclear, because a vector and a DNA construct are synonymous terms defining a circular piece of recombinant DNA. Hence, it is not clear what else the vector "comprises" than the DNA construct. Appropriate correction is required.

At Claim 6, "the DNA construct of claim 4" lacks proper antecedent basis. Claim 4 is directed to a vector.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy J. Nelson whose telephone number is (703) 306-3218. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310. The fax phone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application, or if the examiner cannot be reached as indicated above, should be directed to the Group receptionist whose telephone number is (703) 308-1234.



**AMY J. NELSON, PH.D
PRIMARY EXAMINER**

Amy J. Nelson, Ph.D.

August 10, 2000